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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA ex rel. JORDAN C. SCHNEIDER,	:	Civil Action No. _____
Plaintiff,	:	**JURY TRIAL DEMANDED**
v.	:	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**
PACIRA PHARMACEUTICALS, INC.,	:	
Defendant.	:	**COMPLAINT**

On behalf of the United States of America (the "United States" or "Government"), pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. §§ 3729-3733 (the "FCA"), Relator Jordan C. Schneider makes this Complaint against Defendant Pacira Pharmaceuticals, Inc. ("Pacira").

In support thereof, Relator alleges as follows:

INTRODUCTION

1. Relator brings this action on behalf of the United States, as well as numerous state and local governments, pursuant to the FCA, and analogous state statutes, to recover treble damages and civil penalties arising from Defendant's fraudulent and illegal practices in

promoting sales of its drug Exparel® (also known as bupivacaine liposome injectable suspension) ("EXPAREL"), which is indicated for administration into A surgical site to produce postsurgical analgesia. *See* Exhibit A, Exparel label, at 1. Defendant's conduct violates the FCA.

2. In the course of his employment as a Pharmacy Manager at a hospital in Las Vegas, Nevada, Relator learned first-hand about Defendant's regular pattern and course of illegal and fraudulent conduct in marketing EXPAREL for a number of surgical procedures, all off-label indications not approved by the United States Food and Drug Administration (the "FDA"), and for which EXPAREL may be ineffective

3. This action arises under the provisions of the FCA, and pursuant to the following analogous provisions of state and local law:

Arkansas, Ark. Code Ann. § 20-77-901
California False Claims Act, Cal. Gov't Code § 12651 *et seq.*
Colorado Medicaid False Claims Act, Rev. Stat. § 25.5-4-304 *et seq.*
Connecticut False Claims Act, Chapter 319v § 17b-301a *et seq.*
Delaware False Claims and Reporting Act, Del. Code Tit. 6, § 1201 *et seq.*
Florida False Claims Act, Fla. Stat. § 68-081 *et seq.*
Georgia False Medicaid Claims Act, Ga. Code § 49-4-168 (2007)
Hawaii False Claims Act - False Claims to the State, Haw. Rev. Stat. § 661-21 *et seq.*
Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/1 *et seq.*
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq.*
Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437.1 *et seq.*
Maryland False Claims Act, Md. Code Ann., Health-Gen. § 2-601 *et seq.*
Massachusetts False Claims Act, Mass Laws Ch. 12, § 5(A) *et seq.*
Michigan Medicaid False Claims Act, Mich. Comp Laws Serv. § 400.601 *et seq.*
Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*
Montana False Claims Act, Mont. Code § 17-8-401 *et seq.*
Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. § 357.010 *et seq.*
New Hampshire Medicaid False Claims Act, N.H. Rev. Stat. § 167:61-b *et seq.*
New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*
New Mexico Medicaid False Claims Act., N.M. Stat § 27-14-1 *et seq.*
New York False Claims Act, N.Y. St. Fin. Law § 187 *et seq.*
North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*
Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.*
Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*
Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq.*

Tennessee Medicaid False Claims Act, Tenn. Code § 71-5-181 *et seq.*
Texas Medicaid Fraud Prevention, Tex. Hum. Res. Code § 36.001 *et seq.*
Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq.*
Wisconsin False Claims Act, Wis. Stat. § 20.931 *et seq.*
District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.*
City of Chicago False Claims Act, Mun. Code, § 1-22-010 *et seq.*
New York City False Claims Act, Adm. Code § 7-801 *et seq.*

(collectively, "State *qui tam* statutes")

4. This case arises from false or fraudulent claims for reimbursements for a prescription drug that were submitted or caused to be submitted by Defendant to government-funded programs, including, without limitation, Medicare, Medicaid, the Federal Employees Health Benefits Program, TRICARE/CHAMPUS, and the Veterans Administration in violation of the FCA. The FCA specifically proscribes Defendant's conduct involving unlawful marketing of prescription drugs, and thus the submission of false or non-reimbursable claims to Medicare, Medicaid and other government-funded health programs.

5. This action concerns Pacira's off-label marketing of the pharmaceutical product, Exparel®.

6. EXPAREL is an anesthetic (numbing medicine) that blocks the nerve impulses that send pain signals to an individual's brain. EXPAREL is used as a local (in only one area) anesthetic to numb an area of the body for a minor surgery, such as bunion removal or hemorrhoid surgery.

7. Defendant's off-label and other illegal marketing activities in violation of the FCA and FDA laws and regulations include, but are not limited to:

- systematically engaging in illegal off-label promotion of EXPAREL for numerous surgical procedures as part of a nationwide scheme to grow EXPAREL's sales; and

- providing its sales representatives with improper sales aids and material to distribute to surgeons and other healthcare providers.

8. EXPAREL was only approved by the FDA and launched by Pacira in 2011 and 2012, respectively. However, Pacira has grand ambitions for EXPAREL, namely making it a billon dollar, blockbuster drug as soon as possible.

9. Accordingly, Pacira almost immediately resorted to illegal measures to promote the off-label use of EXPAREL. This nationwide marketing scheme has caused tens of millions of dollars in false claims, and will continue indefinitely if not enjoined from doing so by this Court.

10. Defendant's FCA violations and its various marketing schemes corrupted the independent medical judgment of physicians and other healthcare professionals, unlawfully increased costs to the United States and the *Qui Tam* States for prescription drugs, and risked patients' health by improperly influencing physicians' decisions about whether to prescribe EXPAREL.

11. Defendant knew or should have known that its unlawful activities would cause physicians and other healthcare professionals to routinely file false claims for reimbursement from the federal and state governments in violation of the FCA and state and local law, and involved violations of the Food, Drug and Cosmetics Act, 21 U.S.C. § 301 *et seq*., the Food and Drug Administration and Modernization Act of 1997, 21 U.S.C. § 351 *et seq*. and 21 U.S.C. § 360aaa *et seq*., the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statute, 42 U.S.C. § 1320a *et seq.*, the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, and similar state laws.

12. Because of Defendant's unlawful promotion schemes, patients receiving Defendant's prescription drug EXPAREL for unapproved and unproven uses received no

assurance that their doctors were exercising their independent and fully-informed medical judgment.

13. Defendant's off-label and other illegal marketing practices resulted in substantial loss to the federal and state governments.

JURISDICTION AND VENUE

14. This Court has federal subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732. This Court has supplemental jurisdiction over the counts relating to the state False Claims Acts pursuant to 28 U.S.C. § 1367.

15. Venue for this action is predicated on 31 U.S.C. § 3732(a) which provides that "any action brought under § 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant can be found, resides, transacts business or in which any act prescribed by § 3729 occurred."

16. At all times relevant to this Complaint, Defendant Pacira resided in, maintained permanent employees in, and transacted a substantial amount of business in the District of New Jersey, and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District. Accordingly, Pacira is subject to personal jurisdiction in this State, also.

17. This Court also has supplemental jurisdiction over the States' *qui tam* claims pursuant to 28 U.S.C. § 1367 which provides that "in any civil action of which the district courts have original jurisdiction, the district court shall have supplemental jurisdiction over all claims that are so related to claims in action in such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution."

18. Under the False Claims Act, this Complaint is to be filed *in camera*, remain under seal for a period of at least sixty (60) days and shall not be served on the Defendant until the

Court so orders. The government may elect to intervene and proceed with the action within sixty (60) days after it receives both the Complaint and the material evidence and information.

19. Relator has direct and independent knowledge of the off-label marketing scheme to cause the submission of false claims that is set forth in this Complaint and brings this action on behalf of himself and the United States pursuant tot the relevant provisions of the FCA.

20. On October 8, 2014, Relator's counsel sent, via UPS overnight delivery, a statement containing substantially all material facts underlying the allegations of the Complaint, as required by the FCA, 31 U.S.C. § 3730(b)(2), to the United States Attorney for the District of New Jersey, as well as the United States Attorney for the Eastern District of Pennsylvania.

PARTIES

21. Plaintiff Jordan C. Schneider, until October 24, 2014, was the Pharmacy Clinical Manager at North Vista Hospital in Las Vegas, Nevada. North Vista Hospital is a 177-bed hospital.

22. Relator has been approached and marketed by Pacira sales representatives directly, and seen Pacira sales representatives market directly to physicians, including, but not limited to, numerous surgeons at the hospital.

23. Because Relator had influence at North Vista Hospital over the prescription drugs available, as well as the drugs listed on the hospital's formulary, he was often contacted directly by pharmaceutical sales representatives.

24. Defendant Pacira Pharmaceuticals, Inc. ("Pacira") is a Delaware corporation with its principal executive offices located at 5 Sylvan Way, Suite 100, Parsippany, NJ 07054.

25. Pacira is a specialty pharmaceutical company that develops, commercializes and manufactures pharmaceutical products, based on its proprietary DepoFoam® drug delivery technology, for use in hospitals and ambulatory surgery centers.

26. Pacira's primary product is EXPAREL.

FACTUAL BACKGROUND

STATUTORY AND REGULATORY PROVISIONS APPLICABLE TO PACIRA'S FALSE CLAIMS

A. Federal Government Health Programs

27. Federal, state and local governments, through their Medicaid, Medicare, Tricare, Veteran's Administration and other Government healthcare payors, are among the principal purchasers of Pacira's pharmaceutical products (individual States' Federal Government Health Programs are hereinafter referred to as the "Medicaid Program").

28. Medicare is a federal government health program primarily benefiting the elderly which Congress created in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS").

29. Congress created Medicaid at the same time it created Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program providing payment of medical expenses to low-income patients. Funding for Medicaid is shared between the federal government and state governments. The federal government also separately matches certain state expenses incurred in administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than does Medicare.

30. Medicaid has broad coverage for prescription drugs, including self-administered drugs. Nearly every state has opted to include basic prescription drug coverage in its Medicaid plan.

31. Tricare is the health care system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and career military retirees and their dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. Tricare is a triple-operation benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers.

32. While Tricare treats active duty military and their dependents, the Veterans Administration ("VA") provides health care and other benefits to veterans of the military through its nationwide network of hospitals and clinics.

33. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than eight (8) million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plans. FEHBP plans are managed by the Office of Personnel Management.

B. FDCA and FDA Regulations

34. The FDA regulates drugs based on the "intended uses" for such products. Before marketing and selling a prescription drug, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. § 355(a).

35. The FDA reviews pharmaceutical manufacturers' applications for new drugs to determine whether the drug's intended uses are safe and effective. *See* 21 U.S.C. § 355. Once a drug is approved for a particular use, doctors are free to prescribe the drug of "non-indicated" or off-label purposes. While doctors may independently request information from drug manufacturers about such off-label uses, with very few exceptions, the FDA prohibits drug manufacturers from marketing or promoting drugs for uses, *i.e.* "indications," not approved by the FDA.

36. Thus, under the Food and Drug Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("FDCA"), pharmaceutical manufacturers may not market or promote a drug for a use that the FDA has not approved. 21 U.S.C. §§ 331(a), (d). When a drug is used for a treatment not approved by the FDA, the use is called "off-label

37. "Off-label" refers to the marketing of an FDA-approved drug for uses that have not undergone FDA review and approval, *i.e.*, for purposes not approved by the FDA.

38. While purely scientific or educational programs are permissible, sales and marketing presentations, promotions, or marketing to physicians for uses other than those approved by the FDA are considered off-label marketing or "misbranding" proscribed by the FDA *See* 21 U.S.C. §§ 331(a) – (b), 352(a), (f). Additional proscribed marketing activity includes any attempts by a pharmaceutical sales representative to solicit discussions with physicians concerning off-label use.

39. Strong policy reasons exist for strict regulation of off-label marketing. Off-label promotion bypasses the FDA's strict review and approval process and removes the incentive to obtain definitive clinical study data showing the efficacy and safety of a product and, accordingly, the medical necessity for its use.

40. Pursuant to the FDCA, 21 U.S.C. §§ 301 *et seq.*, the FDA strictly regulates the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies to market and sell FDA-approved prescription drugs.

41. The FDA interprets "labeling" in its regulations broadly to include items that are "1) descriptive of a drug; 2) supplied by the manufacturer or its agents; and 3) intended for use by medical personnel." 21 C.F.R. § 202.1. The FDCA defines both misleading statements and the failure to reveal material facts in a label or product labeling as "misbranding." 21 U.S.C. § 321(n). Labeling includes, among other things, brochures, booklets, detailing pieces, literature, reprints, sound recordings, exhibits and audio visual material. 21 C.F.R. § 202.1(1)(2).

42. FDA regulations deem "advertising" to include advertisements in published journals, magazines, newspapers and other periodicals, and broadcast through media such as television, radio, and telephone communications systems. *See* 21 C.F.R. § 202.1(I)(1). Courts have consistently held that oral statements made by a company's sales representative relating to a pharmaceutical product constitute commercial advertising or promotion. *See Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 7 (7th Cir. 1992) (interpreting Lanham Act).

43. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading "misbrand" a drug in violation of the FDCA, 21 U.S.C. §§301, 321, 331, 352, 360b, 371; C.F.R. § 202.1(e)(6), (e)(7); 21 C.F.R. § 1.21.

44. Such violations exist where promotional marketing materials and presentations (*i.e.* advertisements) for an FDA approved drug, among other things:

- Minimize, understate, or misrepresent the side effects, contraindications and/or effectiveness of the drug;
- Overstate or misrepresent the side effects, contraindications, and/or effectiveness of competing drugs;
- Expressly or implicitly promote uses, dosages or combination usage of the drug that are not contained in the FDA approved labeling (*i.e.*, off-label uses);
- Fail to reveal material facts with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement;
- Contain representations or suggestions, not approved or permitted in the labeling, that the drug is better, more effective, or useful in a broader range of conditions or patients, safer, or has fewer, or less incidence of, or less serious side effects or contraindications than demonstrated by substantial evidence or substantial clinical experience;
- Present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does;
- Use a quote or paraphrase out of context to convey a false or misleading idea; and/or
- Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketing or any competing drug.

See 21 C.F.R. § 202.1(e)(4)(5)(6), and (7).

45. Oral statements and written materials presented at industry-supported activities, including lectures and teleconferences, provide evidence of a product's intended use. If these statements or materials promote a use inconsistent with the product's FDA-approved labeling, the drug is misbranded, as the statements and materials fail to provide adequate directions for all intended uses.

C. The False Claims Act and the Medicare Fraud

46. The federal False Claims Act provides that any person who knowingly presents or causes another to present a false or fraudulent claim for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1)(A)&(B).

47. The States that are party to this Complaint have enacted statutes similar to the FCA that apply to Medicaid fraud and/or fraudulent health care claims submitted for payment by municipal funds.

SPECIFIC ALLEGATIONS OF PACIRA'S FALSE CLAIMS

A. History and Background Relating to EXPAREL

48. EXPAREL is a local analgesic that utilizes bupivacaine (described below) in combination with a product delivery platform, DepoFoam®.

49. Bupivacaine is a local anesthetic belonging to the amino amide group that has been available in the United States since 1972 and is commonly used in surgery due to its rapid onset and longer duration of action compared to other local anesthetics.

50. EXPAREL was approved by the U.S. Food and Drug Administration ("FDA") in October 2011. Pacira launched EXPAREL in January 2012.

51. The INDICATION AND USAGE section of the FDA-approved EXPAREL Prescribing Information, states that:

> EXPAREL is a liposome injection of bupivacaine, an amide-type local anesthetic, indicated for administration into the surgical site to produce postsurgical analgesia.
>
> EXPAREL has not been studied for use in patients younger than 18 years of age.

See Exhibit A, at 2.

52. EXPAREL is administered locally into the surgical site by injection into soft tissues surrounding the surgical site. A single intraoperative injection treats pain at the source with reduced opioid requirements. EXPAREL is available in 20 mL single use vials. *See id*.

53. On April 9, 2012, Pacira published a press release announcing the commercial launch of EXPAREL. In the press release, Pacira stated, in part:

> Pacira Pharmaceuticals, Inc. today announced the commercial launch of EXPAREL ® (bupivacaine liposome injectable suspension) in the United States. Starting today, EXPAREL will begin shipping to hospital and ambulatory care customers through their normal wholesaler and distributor channels. EXPAREL was approved by the U.S. Food and Drug Administration (FDA) in October 2011 for administration into the surgical site to produce postsurgical analgesia.
>
> Strong pre-launch commercialization efforts including more than 40 data publications and more than 1,700 interactions with potential customers have laid the groundwork for what Pacira believes will be the successful introduction of EXPAREL into the hospital marketplace.
>
> "For Pacira, today is the culmination of several important organizational milestones that span the last several years, with the most significant being the FDA approval of EXPAREL," said Dave Stack, president and CEO of Pacira Pharmaceuticals. "For the millions of patients undergoing surgical procedures in the U.S. each year, the introduction of EXPAREL-a single-dose, non-opioid local analgesic given at the close of surgery-represents a significant addition to the armamentarium of currently available options to manage postsurgical pain."
>
> The Pacira sales force, which consists of 63 hospital specialists who cover more than 81 percent of the market Pacira is targeting for EXPAREL, was launched in January 2012. Since that time, this team has been executing a formulary access strategy, working closely with key hospital and surgical customers to initiate the formulary review process to obtain access for EXPAREL.
>
> "Through the work of our field force and the commercialization activities executed to date, awareness and anticipated demand for EXPAREL has continued to grow among our target markets," said Taunia Markvicka, PharmD, vice president, commercial. "We intend to build off that momentum through a targeted strategy in 2012 that encompasses Phase 4 clinical research, partnerships with key hospital customers and robust publication and medical education plans."

54. On May 9, 2012, Pacira published a press release and filed a Form 8-K with the SEC, announcing financial and operating results for the first quarter ended March 31, 2012. In the press release, Pacira stated, in part:

> **About EXPAREL®**
>
> EXPAREL® (bupivacaine liposome injectable suspension) is indicated for administration into the surgical site to produce postsurgical analgesia. The product combines bupivacaine with DepoFoam®, a proven product delivery technology that delivers medication over a desired time period. EXPAREL represents the first and only multivesicular liposome local anesthetic that can be utilized in the peri- or postsurgical setting in the same fashion as current local anesthetics. By utilizing the DepoFoam platform, a single dose of EXPAREL delivers bupivacaine over time, providing analgesia with reduced opioid requirements for up to 72 hours. Pivotal studies have demonstrated the safety and efficacy of EXPAREL in patients undergoing bunionectomy or hemorrhoidectomy procedures and additional studies are underway to further demonstrate the safety and efficacy in other procedures. Additional information is available at www.EXPAREL.com.

51. On August 9, 2012, Pacira issued a press release and filed a Form 8-K with the SEC, announcing financial and operating results for the second quarter ended June 30, 2012. In the press release, Pacira stated, in part:

> "With our first quarter of EXPAREL sales behind us, we are extremely pleased with the launch trajectory and where we are today," said Dave Stack, president and chief executive officer of Pacira. "Based on our sales numbers, initial feedback from the physician community and what we believe to be the market potential for EXPAREL, we feel we have only scratched the surface and look forward to updating you on our commercial success as we expand our market share and explore additional therapeutic indications for EXPAREL."
>
> **EXPAREL Commercialization:** In the second quarter ended June 30, 2012, EXPAREL sales totaled $2.3 million. As of August 3, 2012, 428 accounts had ordered EXPAREL compared to 164 accounts as of May 8, 2012. Among the accounts that have placed an initial order of EXPAREL, 49 percent of the total accounts have now reordered and 55 percent of hospital accounts have reordered.
>
> **Exploring Additional Indications for EXPAREL:** Based on a recent meeting with the U.S. Food and Drug Administration, Pacira currently

> expects to launch a Phase 2/3 clinical program in the second half of 2012 to study the safety and efficacy of EXPAREL for a nerve block indication. Bupivacaine is a standard of care in many nerve block procedures, creating what Pacira believes to be a potential customer base already familiar with the drug and injection techniques.

52. On November 1, 2012, Pacira issued a press release and filed a Form 8-K with the SEC, announcing financial and operating results for the third quarter ended September 30, 2012. In the press release, Pacira stated, in part:

> "We launched EXPAREL in April and have successfully doubled our product sales quarter over quarter with these results," said Dave Stack, president and chief executive officer of Pacira. "In addition, we have completed the build-out of our EXPAREL next generation manufacturing facility ahead of schedule. As such, we are advancing with confidence several important initiatives, including continued exploration of additional therapeutic uses for EXPAREL and strategic marketing programs intended to accelerate growth. We look forward to a strong fourth quarter of 2012."
>
> **EXPAREL Commercialization:** In the third quarter ended September 30, 2012, EXPAREL sales totaled $4.6 million, up from $2.3 million in the second quarter of 2012. As of October 26, 2012, 628 accounts have ordered EXPAREL Compared to 428 accounts as of August 3, 2012. Of these, 58 percent of all accounts have reordered EXPAREL and 63 percent of hospital accounts have reordered. Pacira works with an important mix of customers who are expanding their use with 115 hospitals, which have ordered six times or more and continue to see rapid expansion with an average of 22 new customers ordering each week in the quarter and for the month of October.
>
> **Exploring Additional Indications for EXPAREL:** During the third quarter, Pacira initiated a Phase 2/3 study investigating the use of EXPAREL as a single-dose injection femoral nerve block for total knee arthroplasty surgery. Additionally, Pacira announced data from its first completed Phase 4 IMPROVE study in open colectomy patients, demonstrating that the EXPAREL-based multimodal regimen achieved a statistically significant reduction in each primary endpoint in the study, including a 60 percent reduction in hospital length of stay.

53. On March 7, 2013, Pacira issued a press release and filed a Form 8-K with the SEC, announcing financial and operating results for the year and fourth quarter ended December 31, 2012. In the press release, Pacira stated, in part:

> "The launch of EXPAREL continues to go well. Weekly growth in new customers and continued expansion in hospitals that have gained experience with the product support our belief that EXPAREL provides a significant opportunity to improve patient care as well as hospital economics," said Dave Stack, president and chief executive officer of Pacira. "We are in the fortunate position of hearing daily that clinicians are impressed with the ability of EXPAREL to reduce the requirement for opioids and to control postsurgical pain and that nurses and patients comment on the advantages of EXPAREL."
>
> **EXPAREL Commercialization:** In the fourth quarter ended December 31, 2012, EXPAREL sales totaled $7.8 million, up from $4.6 million in the third quarter of 2012. As of December 31, 2012, 819 accounts ordered EXPAREL, compared to 628 accounts as of October 26, 2012. Of these, 191 accounts reordered EXPAREL six times or more and 110 accounts reordered 10 times or more. Pacira continues its steady expansion since launch with access to 75 percent of the top 100 target hospital accounts and 53 percent of the top 500 target hospital accounts.
>
> *** * * * ***
>
> **Exploring Additional Indications for EXPAREL**: During the fourth quarter, Pacira announced new positive data supporting the use of EXPAREL infiltrated into the transversus abdominis plane (iTAP) in robotic prostatectomy patients. These data showed that treatment with EXPAREL resulted in reduced need for opioids compared to historical controls and 100 percent patient satisfaction with postsurgical pain control. The findings were presented at the 11th Annual American Society of Regional Anesthesia and Pain Medicine (ASRA) Meeting. Additionally, Pacira has two ongoing pivotal Phase 3 trials, an intercostal block study in posterolateral thoracotomy patients and a femoral nerve block in total knee arthroplasty (TKA) patients.

54. On May 8, 2013, Pacira published a press release and filed a Form 8-K with the SEC, announcing financial and operating results for the first quarter ended March 31, 2013. In the press release, Pacira stated, in part:

> "We saw a solid quarter in what was the fourth quarter of our EXPAREL launch," said Dave Stack, president and chief executive officer of Pacira. "We continue to see growth from new customers as well as expansion with existing customers who have had access to the product for some time. Especially important is the recent pattern where we have achieved formulary approval without restrictions for several major centers of influence based on the clinical evidence and the broad base of surgical specialties expressing interest in EXPAREL. At the same time, many early-adopting institutions, where EXPAREL was made available with restrictions, have removed these

> restrictions based on their success in utilizing reduced opioid pain management strategies."
>
> **EXPAREL Commercialization:** In the first quarter ended March 31, 2013, EXPAREL sales totaled $10.4 million, up from $7.8 million in the fourth quarter of 2012. As of March 31, 2013, 1,065 accounts ordered EXPAREL, compared to 819 accounts as of December 31, 2012. Of these, 308 accounts ordered EXPAREL six times or more and 175 accounts ordered 10 times or more. Pacira continues its steady expansion since launch with an average of 22 new customers per week as of March 31, 2013.
>
> **EXPAREL as Part of a Multimodal Approach to Postsurgical Pain Management:** Recently published national and regional analyses of more than 400,000 patients receiving opioids for postsurgical pain management show that patients who experienced opioid-related adverse events (ORAEs) had longer lengths of hospital stay, higher costs of care, greater rates of 30-day readmission to the hospital and a significantly increased risk of mortality. Although opioids have long been the mainstay of postsurgical pain control, these analyses are part of a growing body of evidence that suggests the need to reexamine the benefit-risk profile of an opioid-centric pain management paradigm and to explore a multimodal approach that uses alternative modalities to decrease the amount of opioids needed.
>
> **Recent Data Supporting the Utility of EXPAREL Among Surgical Audiences**: Last month, Pacira announced results from EXCLAIM, its Phase 4 prospective, observational study, to assess the use of EXPAREL for postsurgical analgesia in patients undergoing four common plastic surgery procedures.

55. On August 6, 2013, Pacira issued a press release and filed a Form 8-K with the SEC, announcing financial and operating results for the second quarter ended June 30, 2013.

56. In the press release, Pacira stated, in part:

> "The second quarter marks the commencement of the second year of launch, and we are pleased with the strong sales growth and traction of EXPAREL," said Dave Stack, president, chief executive officer and chairman of Pacira. "Broad market acceptance across a wide range of surgical specialties, bolstered by a series of commercial initiatives and a growing body of clinical evidence, has led to formulary approval and expanded access among both existing and new customers alike."

57. On October 31, 2013, Pacira issued a press release and filed a Form 8-K with the SEC, announcing financial and operating results for the third quarter ended September 30, 2013.

58. In the press release, Pacira stated, in part:

> "The strong third quarter for EXPAREL sales was accelerated by increased traction in orthopedic surgeries and infiltration into the transversus abdominis plane (or *iTAP*) procedures," said Dave Stack, president, chief executive officer and chairman of Pacira. "Driven by strategic partnerships, specialized education and training, as well as new clinical evidence, we are changing the standard of care for postsurgical pain management across different surgical specialties and audiences."
>
> **EXPAREL Commercialization:** In the third quarter ended September 30, 2013, EXPAREL sales totaled $20.0 million, up from $15.2 million in the second quarter. Pacira continued its steady expansion of EXPAREL sales, reporting 297 total new accounts in the third quarter, an average of 23 new customers per week. As of September 30, 2013, 1,732 total accounts ordered EXPAREL since launch, with 165 accounts each ordering more than $100,000. The customer base has continued to grow along with acceptance and use of EXPAREL in hospitals that adopted the product early in the launch.

59. On February 25, 2014, Pacira issued a press release and filed a Form 8-K with the SEC, announcing financial and operating results for the year and fourth quarter ended December 31, 2013.

60. In the press release, Pacira stated, in part:

> "We are very pleased with the overall performance and trajectory that we have seen in the marketplace for EXPAREL this past year," said Dave Stack, president, chief executive officer and chairman of Pacira. "Driven by the increase in sales among existing accounts as well as new customers purchasing EXPAREL, we saw a surge across all procedure types, with orthopedic and infiltration into the transversus abdominis plane (iTAP) procedures fueling rapid growth."
>
> **EXPAREL Commercialization:** EXPAREL net product sales were $76.2 million in 2013, compared to $14.6 million in 2012, and EXPAREL net sales in the fourth quarter of 2013 were $30.5 million, up from $7.8 million in the fourth quarter of 2012. Since launch, 2,106 total accounts have ordered EXPAREL as of December 31, 2013, with approximately 250 accounts each ordering more than $100,000. Pacira also reported 374 new accounts in the fourth quarter of 2013, averaging approximately 29 new accounts per week.

61. On July 31, 2014, Pacira issued a press release and filed a Form 8-K with the SEC, announcing financial and operating results for the second quarter ended June 30, 2014.

62. In the press release, Pacira stated, in part:

> "With nine quarters now under our belt, we are pleased with the continued success of EXPAREL in the marketplace, both in new accounts as well as within existing accounts," said Dave Stack, president, chief executive officer and chairman of Pacira. "With consistent quarter over quarter growth, an anticipated nerve block indication next year and expanded manufacturing capacity, we believe EXPAREL is well positioned to become a blockbuster drug over the next several years."
>
> **EXPAREL Commercialization:** EXPAREL net product sales were $44.9 million in the second quarter of 2014, compared to $15.2 million in the second quarter of 2013. Pacira also reported 363 new accounts ordering EXPAREL in the second quarter of 2014, averaging 28 new accounts per week. Since launch, 2,815 total accounts have ordered EXPAREL through June 30, 2014, with 469 accounts each ordering more than $100,000 worth of product.
>
> *** * * * ***
>
> **Data Continues to Support Value of EXPAREL-Based Multimodal Regimen for Postsurgical Pain Control:** Last month, Pacira announced the published results from the IMPROVE program, a series of open-label, Phase 4 clinical studies comparing postsurgical narcotic use and health economic outcomes between patients receiving EXPAREL as the basis of a multimodal analgesic regimen versus a standard opioid-based pain management regimen across three surgical procedures—open colectomy, lap colectomy and ileostomy reversal. Published in the Journal of Pain Research, the study showed that the EXPAREL group experienced statistically significant reductions in total narcotic consumption, incidence of opioid-related adverse events (ORAEs), total hospital costs and length of hospital stay by 1.4 days.

63. Based on its own internal numbers. EXPAREL's sales have grown dramatically since April 2012:

2Q 2012	$2.3 million
3Q 2012	$4.6 million
4Q 2012	$7.8 million
1Q 2013	$10.4 million
2Q 2013	$15.2 million
3Q 2103	$20.0 million
4Q 2013	$30.5 million
1Q 2014	$34.4 million
2Q 2014	$44.9 million
3Q 2014 =	$50.2 million

TOTAL SALES 2012 = $14.6 million
TOTAL SALES 2013 = $76.2 million
TOTAL SALES 2014 (as of 10/30/14) = $129.5 million

B. Pacira's Misconduct and Illegal Schemes Relating to EXPAREL

64. Since its introduction to the market, Pacira has overstated the efficacy of its EXPAREL; improperly promoted EXPAREL by touting its ability to be effective for up to 72 hours, when in fact, it is approved only for 24 hours of pain relief; and improperly claimed that EXPAREL is safe for use in numerous surgery procedure, including, but not limited to, knee replacements, and cholecystectomy and colectomy procedures, when in fact, approved labeling does not provide instructions for, or indicate that EXPAREL will be safe and effective for, postsurgical pain, if used in surgical procedures other than hemorrhoidectomy or bunionectomy.

64. On September 22, 2014, the Department of Health & Human Services' ("HHS") Office of Prescription Drug Promotion sent a Warning Letter to Dave Stack, the President and CEO of Pacira referencing certain promotional materials related to EXPAREL. *See* Exhibit B.

65. The Warning Letter was sent to Pacira in response to, among other things, educational technique flashcards and a journal ad for EXPAREL submitted by Pacira as part of a Form 2253 submission.

66. In the Warning Letter, HHS stated that it had evidence that EXPAREL has been marketed for new uses for which it does not have approval, and for which its labeling does not provide adequate directions for use, thus rendering Exparel "misbranded":

- "The administration guides provide evidence that Exparel is intended for new uses for which it lacks approval, and for which its labeling does not provide adequate directions for use, ..."

- "[T]he journal ad is false or misleading because it overstates the efficacy of Exparel."

Exhibit B, at 1.

67. The Warning Letter also states that:

> the DOSAGE AND ADMINISTRATION section of the PI provides recommended dosing for bunionectomy and hemorrhoidectomy only.
>
> * * * * *
>
> The approved labeling for Exparel does not provide instructions for, or otherwise indicate that Exparel will be safe and effective for postsurgical pain if used in surgical procedures other than hemorrhoidectomy or bunionectomy.

See id. at 3.

68. The Warning Letter also states that:

> the inclusion of disclaimers or disclosures, whether in the body of the promotional pieces or a footnote, do not mitigate the overwhelming impression that Exparel is safe and effective for use in cholecystectomy and colectomy. In sum, these presentations provide evidence that Exparel is intended for new uses for which it lacks approval, and for which its labeling does not provide adequate instructions for use.

See id.

69. Further, the Warning Letter noted that a journal advertisement by Pacira claimed EXPAREL was able to provide pain-relief for up to 72 hours, while the drug is approved for pain relief only up to 24 hours. HHS said these claims overstate EXPAREL's efficacy and are misleading.

70. Finally, HHS admitted that it:

> was concerned with Pacira's suggestions, made in an array of professionally-directed promotional materials submitted under cover FDA-form 2253, not discussed within this letter, that Exparel has been demonstrated to be safe and effective in various other surgical procedures (e.g., knee arthroplasty, gastric sleeve, open hysterectomy, lumbar interbody fusion, abdominoplasty, etc.). These additional materials suggest an extensive promotional campaign by Pacira to promote the use of Exparel in surgical procedures other than those for which the drug has been shown to be safe and effective.

71. HHS said that the approved labeling for EXPAREL does not provide instructions for, or indicate that Exparel will be safe and effective for postsurgical pain, if used in surgical procedures other than hemorrhoidectomy or bunionectomy.

72. Relator has evidence of an "extensive promotional campaign by Pacira" for off-label uses.

73. Relator has been approached and marketed by Pacira sales representatives directly, and seen Pacira sales representatives market directly to physicians at North Vista Hospital.

74. Because Relator had enormous influence at the hospital over the prescription drugs available, as well as the drugs listed on the hospital's formulary, he was often contacted directly by pharmaceutical sales representatives.

75. In addition, due to his positon, Relator served as the liaison between doctors at the hospital and Pacira sales representatives. Despite Relator's instructions to the Pacira sales representatives, to limit their sales and marketing activities, they would often market and promote EXPAREL directly to a number of surgeons outside of EXPAREL's indication, including orthopedic surgeons, bariatric surgeons and orthopedic spine surgeons.

76. Relator has been marketed to directly, or has seen Pacira sales representatives market, EXPAREL for the following procedures, none of which are indications for the drug:

- Bariatric surgery;
- Orthopedic procedures (i.e., knee and hip replacement);
- Hernia repair surgery; and
- Spine surgery.

77. Relator describes the Pacira sales representatives conduct as "chasing the surgeons."

78. North Vista Hospital has been identified as a Bariatric Center of Excellence by the American Society for Metabolic and Bariatric Surgery, so its bariatric surgeons, including Thomas Umbach, M.D., FACS, and Bernie Hanna, M.D., FACS, were prime targets for Pacira. Relator observed Pacira sales representatives marketing EXPAREL to Dr. Umbach.

79. Similarly, Relator observed Pacira sales representatives marketing EXPAREL to Mark Kabins, M.D., an orthopedic spine surgeon, Wesley Johnson, M.D., an orthopedic surgeon, and Mary Ann Shannon, M.D., an orthopedic surgeon.

80. Indeed, North Vista's Pharmacy and Therapy committee ("P&T committee") was forced to restrict EXPAREL use due to its over-use in the hospital, which was a direct result of Pacira's overzealous promotional efforts. Relator and Stephen Vargo, M.D., a general surgeon and the Chair of North Vista's P&T committee, attended a dinner sponsored by Pacira relating to the launch of EXPAREL where numerous uses of EXPARE: were discussed.

81. In addition, Relator has observed Pacira sales representatives in the Operating Room with surgeons, although he does not have knowledge as to whether the approval of the patients was obtained.

82. Similarly, an Executive Summary describing EXPAREL and distributed by Cardinal Health, Inc., a health care services company that distributes pharmaceuticals and medical devices, states – "FDA-approved dosing is specific to bunionectomy and hemorrhoidectomy only and is dependent on surgical site and volume required to cover the area."

83. The same Executive Summary continued, "Clinical trials have not identified a safe and effective dose for the off-label use in inguinal hernia, breast augmentation and orthopedic surgeries."

84. In its "Points to Consider", the Executive Summary noted that "Lack of FDA approved dosing and data to support specific dosing for many studied indications."

85. Relator was provided with numerous pieces of promotional pieces by Pacira sales representatives, including, but not limited to:

- A glossy "Administration Technique Guide" for a **partial knee replacement**.

- An article, entitled "Impact of Local Administration of Liposome Bupivacaine for Postsurgical Analgesia on Wound Healing: A Review of Data From Ten Prospective, Controlled Clinical Studies", from *Clinical Therapeutics* (March 2013). Of the ten studies focus in this article, two of them were inguinal hernia repair, two were total knee arthroplasty and two were breast augmentation. None of these surgical procedures are included in the FDA's indications.

- An article, entitled "Bupivacaine Extended-Release Liposome Injection Exhibits a Favorable Cardiac Safety Profile", from *Regional Anesthesia and Pain Medicine* (March-April 2012).

- An article, entitled "A Two-Year Observational Study Assessing the Safety of DepoFoam Bupivacaine After Augmentation Mammaplasty", from *Aesthetic Surgery Journal* (February 2012).

    - Although Pacira has include language that "the information contained within this article is outside the confines of the label for EXPAREL", Relator believes that he was provided this article by Pacira sales representatives without requesting information on this subject.

- An article, entitled "Improving Patient Outcomes through Advanced Pain Management Techniques in Total Hip and Knee Arthroplasty", from *The American Journal of Orthopedics* (October 2013).

- An article, entitled "Extended pain relief trial utilizing infiltration of Exparel®, a long-acting multivesicular liposome formulation of bupivacaine: a Phase IV health economic trial in adults patients undergoing open colectomy", from *Journal of Pain Research* (2012).

- An article, entitled "Bupivacaine liposome injectable suspension compared with bupivacaine HCl for the reduction of opioid burden in the postsurgical setting", from *Current Medical Research & Opinion* (October 2012). This article discussed the use of EXPAREL in inguinal hernia repair, total knee arthroplasty and breast augmentation.

- Although Pacira has included language that "the information contained within this article is outside the confines of the label for EXPAREL", Relator believes that he was provided this article by Pacira sales representatives without requesting information on this subject

- An article entitled "Bupivacaine Extended Release Liposome Injection Does Not Prolong QTc Interval in a Thorough QT/QTc Study in Healthy Volunteers", from *The Journal of Clinical Pharmacology* (November 2011).

86. Relator was also provided, by a Pacira sales representative, with a 2013 article that discussed the adverse side effects arising from patients treated for post-surgical pain with opioids. This comparison study was provided with language touting the efficacy of EXPAREL versus opioids.

87. Daryl E. Kirby, CVP, a Clinical Education Specialist from Pacira, also provided a glossy brochure that discussed the efficacy of EXPAREL "for up to 72 hours."

88. Moreover, a Pacira sales representative recently offered Relator the opportunity to participate in a study, which would include a grant to the hospital. North Vista Hospital refused to permit Relator to participate in the study, citing a conflict of interest.

89. EXPAREL is identified by National Drug Code ("NDC") 65250-266-20.

90. In August 2014, Pacira announced that EXPAREL net product sales were $44.9 million in the second quarter of 2014, compared to $15.2 million in the second quarter of 2013.

91. Pacira expects EXPAREL to grow to a $1 billion product. See http://www.streetinsider.com/Analyst+Comments/Pacira+Pharmas+(PCRX)+Exparel+Could+Be+$1+Billion+Product/7887062.html.

92. At North Vista Hospital, EXPAREL costs approximately $300 per procedure.

93. CardinalHealth, in 2014, stated that the cost of EXPAREL was $285.00 per dose. In comparisons, bupivacaine was only $1.50 to $1.80 per dose.

94. Accordingly, the use of EXPAREL has the potential to increase medication costs dramatically in surgeries that were previously using bupivacaine.

95. Pacira offers a "Reimbursement Guide" for EXPAREL, which is available on its website. *See also* http://www.exparel.com/pdf/Exparel-Billing-Guide3-20-14-FINAL-(Final).pdf.

96. Relator alleges that the misconduct and illegal promotion described above are part of a nationwide scheme by Pacira to increase EXPAREL's sales and market growth.

COUNT I
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

99. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

100. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(l)(A).

101. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented false or fraudulent claims for the improper payment or approval of EXPAREL.

102. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant caused, paid for claims that otherwise would not have been allowed.

103. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT II
Federal False Claims Act, 31 U.S.C. § 3729(a)(l)(B)

104. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

105. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(l)(B).

106. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim for the improper payment or reimbursement of EXPAREL.

107. The United States, unaware of the falsity or fraudulent nature of the claims that Defendant has caused, paid for claims that otherwise would not have been allowed.

108. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT III
Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901

109. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

110. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901.

111. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Arkansas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

112. The Arkansas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

113. By reason of these payments, the Arkansas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT IV

California False Claims Act, Cal. Gov't Code § 12651 *et seq.*

114. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

115. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code § 12651 *et seq.*

116. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the California Medicaid Program (i.e., Medi-Cal) false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

117. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

118. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT V
Colorado False Claims Act, N.Y. St. Finance Law §187 et seq.

119. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

120. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. St. Finance Law §187 *et seq.*

121. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

122. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

123. By reason of the Defendant's unlawful acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

COUNT VI
Connecticut False Claims Act, Conn. Code § 17b-301b *et seq.*

124. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

125. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Code § 17b-301b *et seq.*

126. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Connecticut Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

127. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

128. By reason of these payments, the Connecticut Medicaid Program has been damages, and continues to be damaged in a substantial amount.

COUNT VII
Delaware False Claims Act, Del. Code Ann. tit. 6, § 1201 *et seq.*

129. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

130. This is a claim for treble damages and civil penalties under the Delaware False Claims Act, Del Code Ann. tit. 6, § 1201 *et seq.*

131. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Delaware Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

132. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

133. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VIII
Florida False Claims Act, Fla. Stat. Ann. 5 68.081 *et seq.*

134. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

135. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*

136. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Florida Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

137. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

138. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT IX
Georgia False Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

139. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

140. This is a claim for treble damages and civil penalties under the Georgia False Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

141. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Georgia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

142. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

143. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT X
Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*

144. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

145. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*

146. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

147. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

148. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XI
Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 17511 *et seq.*

149. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

150. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 17511 *et seq.*

151. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Illinois Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

152. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

153. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XII
Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5

154. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

155. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5.

156. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Indiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

157. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

158. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIII
Louisiana Medical Assistance Programs Integrity Law,
La. Rev. Stat. Ann. § 46:439.1 *et seq.*

159. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

160. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.*

161. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

162. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

163. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIV
Maryland False Claims Act, Md. Code Ann. §2-601 *et seq.*

164. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

165. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act of 2010, Md. Code Ann. § 2-601 *et seq.*

166. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Maryland Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

167. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

168. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XV
Massachusetts False Claims Act, Mass. Ann. Laws ch. 12,§ 5(A)-(O)

169. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

170. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12,§ 5(A)-(O).

171. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

172. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

173. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVI
Michigan Medicaid False Claims Act,
MCLA §§ 400.601

174. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

175. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, MCLA, §§ 400.601.

176. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Michigan Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

177. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

178. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVII
Minnesota False Claims Act, § 15C.01 *et seq.*

179. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

180. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, § 15C.01 *et seq.*

181. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

182. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

183. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVIII
Montana False Claims Act, Mont. Code Ann. § 17-8-401

184. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

185. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann. § 17-8-401.

186. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Montana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

187. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

188. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIX
Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*

189. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

190. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq*.

191. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Nevada Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

192. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

193. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XX
New Hampshire Medicaid Fraud and False Claims,
N.H. Rev. Stat. Ann. § 167:61-b, *et seq.*

194. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

195. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. § 167:61-b, *et seq.*

196. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

197. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

198. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXI
New Jersey False Claims Act
N.J. Stat. §§ 2A:32C-1 *et seq.*

199. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

200. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq.*

201. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

202. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

203. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXII
New Mexico Medicaid False Claims Act,
N.M. Stat. Ann. 1978, § 27-14-1 *et seq.*

204. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

205. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. 1978, § 27-14-1 *et seq.*

206. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

207. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

208. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIII
New York False Claims Act, N.Y. State Fin. Law § 187

209. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

210. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law § 187.

211. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the New York Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

212. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

213. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIV
North Carolina False Claims Act, N.C.G.S §§1-605 *et seq.*

214. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

215. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S §§1-605 *et seq.*

216. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

217. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

218. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXV
Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053

219. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

220. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053.

221. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

222. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

223. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVI
Rhode Island False Claims Act, R.I. Gen Laws § 9-1.1-3 *et seq.*

224. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

225. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen Laws § 9-1.1-3 *et seq*.

226. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

227. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

228. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVII
Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* and Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.*

229. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

230. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and the Tennessee False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*; Tenn. Code Ann. § 4-1 8-101 *et seq.*

231. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

232. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

233. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVIII
Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

234. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

235. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

236. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Texas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

237. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

238. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIX
Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*

239. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

240. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-21 6.1 *et seq.*

241. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Virginia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

242. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

243. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXX
Wisconsin False Claims for Medical Assistance Act,
Wis. Stat. §§ 20.931 *et seq.*

244. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

245. This is a claim for treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §§ 20.931 *et seq.*

246. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

247. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

248. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXI
Chicago False Claims Act, § 1-22-010 *et seq.*

249. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

250. This is a claim for treble damages and civil penalties under the Chicago False Claims Act, § 1-22-010 *et seq.*

251. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the City of Chicago Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

252. The City of Chicago Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

253. By reason of these payments, the City of Chicago Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

254. Upon information and belief, Defendant is a "city contractor" as that phrase is defined in the Chicago Municipal Code, § 1-22-030.

COUNT XXXII
New York City False Claims Act
New York City Administrative Code §7-801-§7-810

255. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

256. This is a claim for treble damages and penalties against the Defendant on behalf of the City of New York under the New York City False Claims Act, New York City Administrative Code §7-801-§7-810.

257. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the City of Chicago Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

258. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York City Government to approve and pay such false and fraudulent claims.

259. The New York City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid

and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.

260. By reason of the Defendants' unlawful acts, the City of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

COUNT XXXIII
District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq.*

261. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

262. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code 5 2-308.14 *et seq.*

263. By virtue of the off-label marketing and illegal promotion described above, Defendant knowingly presented or caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

264. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

265. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

WHEREFORE, Relator requests that judgment be entered against Defendant, ordering that:

(i) Defendant ceases and desists from violating the False Claims Act, 31 U.S.C. 3 3729, *et seq.*, and the State False Claims Acts;

(ii) Defendant pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has

sustained because of Defendant's actions, plus the appropriate amount to the States under similar provisions of the State False Claims Acts;

(iii) Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts;

(iv) Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 3 1 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts;

(v) Defendant be penalized in accordance with the Medicare Anti-Kickback Statute, as amended by the Balanced Budget Act of 1997, for each anti-kickback violation;

(vi) Defendant be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

(vii) Defendant disgorge all sums by which it has been enriched unjustly by its wrongful conduct; and

(viii) The United States, the States, and Relator recover such other relief as the Court deems just and proper.

JURY TRIAL DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator demands a jury trial.

Respectfully submitted,

Dated: November 6, 2014

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